DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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cc: HFI-35/FOI Staff
DWA

April 12, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 25

Richard A. Guerts
President
Pro Chemicals, Inc.
301 Bridge Street
Green Bay, Wisconsin 54303

Dear Mr. Guerts:

During our inspection of your Pro Chemicals, Inc. human and veterinary drug manufacturing facility located in Green Bay, Wisconsin, our investigator found serious violations of the current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Your human and veterinary drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The violations observed during our inspection include but are not limited to the following:

1. Failure to assure uniformity from batch to batch. Master production and control records for each drug product, including batch size thereof, have not been prepared, dated and signed (full signature, handwritten) by one person and independently checked, dated and signed by a second

person. Failure to describe in a written procedure the preparation of master production and control records (21 CFR 211.186). For example, your master production and control records are incomplete.

2. Failure to prepare batch production and control records containing complete information relating to the production and control of each batch for each batch of drug product produced (21 CFR 211.188). For example, your current records do not include an accurate reproduction of the master production and control record, dated and signed, and documentation that each significant step in the manufacturing, processing, packing of, or holding was accomplished.

3. Failure to have all drug product production and control records, including those for packaging and labeling, reviewed and approved by the quality control unit to determine compliance with all established, approved procedures before a batch is released or distributed (21 CFR 211.192). For example, there is no record of review and approval by your quality control unit of your drug batch production and control records.

4. Failure to conduct at least one test to verify the identity of each component of drug product [21 CFR 211.84(d)(1)]. No identity tests have been performed on incoming components.

5. Failure to test each component for conformity with all appropriate written specifications for purity, strength, and quality and/or failure to receive a report of analysis from the supplier of the component [21 CFR 211.84 (d)(2)]. For example, all incoming ingredient components, containers and closures for drug products have not received appropriate tests as defined by specification and/or certificates of analysis (COA).

6. Failure to have written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures [21 CFR 211.80]. Appropriate written specifications, standards, sampling plans, test procedures or other laboratory control mechanisms

have not been established for all components, containers, drug products, etc.

7. Failure to have appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release, for each batch of drug product produced [21 CFR 211.165]. For example, no analysis has been made to determine conformance to identity and strength of the active ingredient in the finished product.

Section 510 of the Act requires every person upon first engaging in the manufacture, preparation, etc., of a drug or drugs shall immediately register and list the drug products manufactured, prepared, etc. Failure to register and list the drug products manufactured at your facility misbrands your products within the meaning of Section 502(o) of the Act. Although you are registered as a human drug manufacturer, you should also register as a veterinary drug manufacturer due to the veterinary drug products your firm manufactures. When you receive your annual drug establishment re-registration forms in the mail, you can add the veterinary drug manufacturing information to the form.

The potency analysis of your Iodine Pre-Dip is outside your quality control range of ~~~~~ titratable iodine. Your product was found to contain 122% of the declared titratable iodine (0.25%). This misbrands your product in that it is false and misleading. This is also a further indication of your lack of controls during the manufacturing process.

In addition, your products are also misbranded within the meaning of Section 502(b)(2) of the Act in that their labeling fails to bear an accurate statement of the net contents in terms of weight, measure, or numerical count.

Please be aware we have submitted copies of your labels to the Center for Veterinary Medicine for their review and comment. We will forward to you any comments we receive from the Center.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with

each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that FDA expects all your locations to be in compliance.

You should notify this office in writing within 15 working days of receipt of this letter of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/ccl